The FDA Docket

Making your voice heard at FDA

Overview

- Why it matters
- What is a docket and how is a docket used?
- Making a submission
- Suggestions for effective comments
- Practice
- Questions?

FDA mission: to promote and protect the public health

- Your input helps FDA to better understand how proposed policy actions may impact diverse populations
- Opportunity to support FDA action or raise important issues that may not have been considered in the agency's initial deliberations

FDA requests public comments when establishing or modifying how food, medical products and/or medical devices are regulated by the agency.

You can provide feedback by commenting on:

- Proposed **rules** (also called **regulations**) which have the force and effect of law;
- **Guidance documents**, or statements of our current thinking on a topic.

FDA also conducts **public meetings** and **hearings** where you can learn about and get your opinions on record about various topics.

What is a docket and how is it used?

Docket: A collection of documents or information related to an agency rulemaking or other action; the public record for the action.

What's in a docket?

- Rules and notices published in the *Federal Register*
- Analyses and materials referenced in those documents
- Public comments
- Hearing transcripts
- Petitions

Finding and Commenting on a Docket

Search for rules or guidance documents by keyword, title, or docket # at www.regulations.gov

Example:
"deeming"

Click “Comment Now”

Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products

- Document Contents : ...Services ---------- Food and Drug Administration ---------- 21 CFR Parts 1100, 1140, and 1143 Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic...

Proposed Rule by **FDA** on **04/25/2014** ID: FDA-2014-N-0189-0001

Comment Now!

Due Jul 09, 2014 11:59 PM ET

Open Docket Folder

RIN: 0910-AG38

You are commenting on:

The **Food and Drug Administration** (FDA) Proposed Rule: **Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products**

For related information, **Open Docket Folder**

1 Your Information

1 Your Information | 2 Your Preview | 3 Your Receipt

Information entered will be viewable on Regulations.gov

View Commenter's Checklist (PDF) | Alternate Ways to Comment

REQUIRED

Comment (Required)

5000 characters remaining

Optional

Upload file(s) (Optional)

Choose file

Optional

First Name **Last Name**

I want to provide my contact information

I am submitting on behalf of a third party

Category (Required)

REQUIRED

Select a Category...

Continue

Get email alerts about new dockets from the Federal Register:

https://www.federalregister.gov/my/sign_up

Making a submission to the docket (mail/hand delivery/courier)

See notice in the Federal Register for the appropriate address and contact person

Written Submissions

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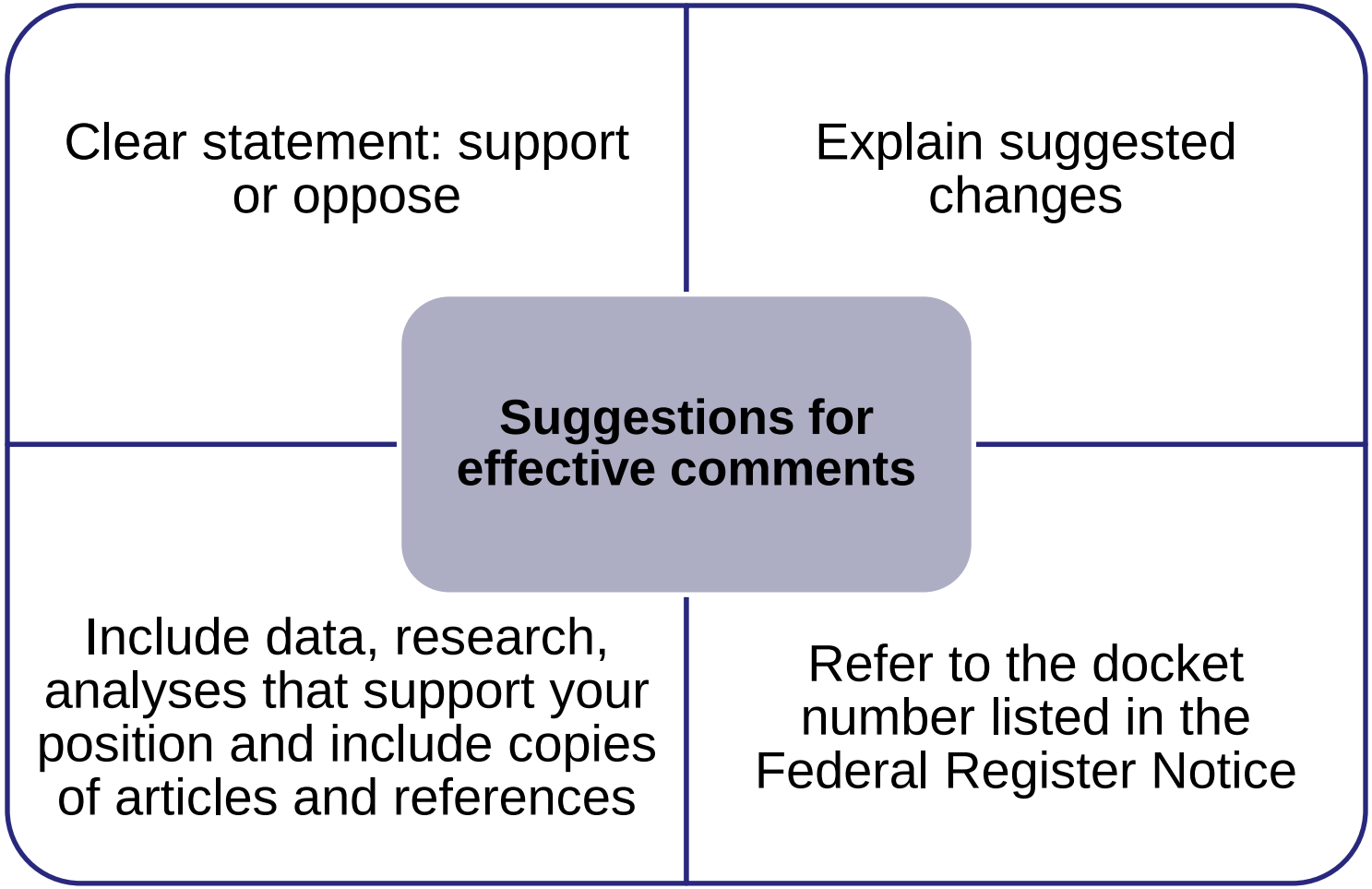
Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name, Docket No. FDA-2014-N-0189, and RIN 0910-AG38 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the SUPPLEMENTARY INFORMATION section.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, fo und in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Suggestions for writing better comments


Clear statement: support or oppose
Explain suggested changes
Suggestions for effective comments
Include data, research, analyses that support your position and include copies of articles and references
Refer to the docket number listed in the Federal Register Notice

Tips for commenting:

- Write down your Comment Tracking Number
- You will have the opportunity to preview your comment before submitting

If you miss a deadline:

- You can mail in your comments after the deadline
- You can request an extension for the docket

You can review a docket:

- www.regulations.gov
- FDA Dockets Management's reading room (Room 1061, 5630 Fishers Lane, Rockville, MD)

FDA considers public comments when drafting the final rule.

Learn more http://go.usa.gov/JNNY

Practice: Identifying Health Disparities Docket

- Search docket #XXX at www.regulations.gov
- Click “Comment Now”
- Comment, review, and submit!

References

http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194912.htm

http://www.regulations.gov/#!help

http://www.regulations.gov/#!faqs

Questions?

- FDA Dockets Management (Monday-Friday, 9 -4 EST): 301-827-6860
- For complaints and disputes, contact the Ombudsman, Lawrence “Jake” Romanell: *Lawrence.Romanell@fda.hhs.gov*

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www.fda.gov/minorityhealth